REMARKS

This paper is responsive to the Office Action dated January 13, 2005, which is the second non-final action on the merits of the application.

Claims 1-7 and 9-21 were previously pending in this application. Claims 1-7, 9-17, and 17-21 were under examination, and stand variously rejected. Claim 22 has been added, and other claims are reworded. Accordingly, claims 1-7, and 9-22 are now pending. Claims 18-20 are still withdrawn from examination, but are subject to a request for rejoinder.

Further consideration and allowance of the application is respectfully requested.

Interview Summary:

The undersigned wishes to express his gratitude to Examiner Malgorzata Walicka and Examiner Rebecca Prouty for the helpful and constructive interview held by telephone on Friday, June 3, 2005. Amendments and remarks discussed during the interview are incorporated into this response.

Amendments:

The amendments to the specification do not incorporate new matter into the disclosure. The amendments on page 2 tidy up some clerical errors. The three paragraphs inserted on page 7 are adapted from U.S. Patent 6,166,178 (application 08/974,549): specifically, col. 45 (lines 7-12); col. 49 (lines 15-17 and 29-32); col. 71 (line 53) to col. 72 (line 12); col. 89 (lines 40-46); and col. 90 (lines 19-22). The '178 patent was incorporated into the present disclosure by reference (application 08/974,549) in the second paragraph of the specification as filed.

The amendments to the claims also do not incorporate new matter, being supported throughout the specification and the claims as previously presented. The deletion range 326-415 (claims 1-3, 5, and 16-17) is supported in Table 1 of the specification (192-450, minus 192-326 + 415-450). Reference to a [TRT mutant] polypeptide inhibiting telomerase enzyme activity when introduced into a cell expressing hTRT is made in the substitute specification on page 3, lines 1-3. Reference to use of hTRT peptides for making antibody (claims 2 and 3) is disclosed in the '178 patent, incorporated into this application by reference, and presented herein in the amendments to the specification. Amended claim 5 derives support from claims 3 and 4 as previously presented. New claim 22 is supported *inter alia* at page 6, lines 12-14 of the substitute specification.

Objections:

Table 1 of the specification was objected to in the Office Action for not indicating the ability of each of the mutant forms of TRT to bind RNA component, bind human telomeres, or act as a dominant negative mutant. Claim 5 has now been amended to eliminate use of the term *dominant negative mutant.* Claims 14 and 15 have been amended to qualify the claimed product not as having a *means* for binding telomeres or telomerase RNA component, but merely as having these as a functional property. The skilled reader may readily determine whether a product has the function recited in these dependent claims for herself on an empirical basis. Accordingly, the objections to Table 1 are now moot.

The claims have also been amended so as to resolve the objections made to the claims. Applicant thanks the Examiner for these helpful suggestions.

Rejections under 35 USC § 112 ¶ 2:

Applicant gratefully acknowledges withdrawal under 1.112 ¶ 2 of the rejection of claims 1, 16, 5-7, and 13-17.

Certain claims still stand rejected under this paragraph for use of the transitional phrase *consisting essentially of.* The claims have now been further amended in a manner that is believed to resolve all outstanding difficulties.

- Claims 1, 4, and 16 as amended no longer uses the phrase.
- Claims 2 and 3 cover a polypeptide *consisting essentially of* at least 500 amino acids of SEQ. ID NO:2, except for the deletion(s) specified. This means that the polypeptide may contain additional residues outside the deleted regions, as long as the additional residues do not interfere with the ability of the polypeptide to elicit an hTRT antibody as required.
- Claims 3, 5, and 17 also refers to particular deleted regions *consisting essentially of* exact ranges of amino acid residues. This means that the deletion(s) of residues from SEQ. ID NO:2 may be a few amino acids shorter or longer than the specified range, as long as the polypeptide having the deletion(s) still lacks telomerase catalytic activity when associated in telomerase RNA component.

- Claims 18-20 cover a peptide, polypeptide, or peptide mimetic containing a telomerase inhibition means that *consists essentially of* particular peptide sequences. This means that the sequence may contain additional residues or a substitution that does not interfere with the ability of the claimed product to inhibit human telomerase catalytic activity.

Withdrawal of these rejections is respectfully requested.

Rejections of claims 1-7 and 16-17:

These claims stand rejected under the written description requirement of § 112 ¶ 1. The Office Action suggests that the amended claims contain new matter: specifically, the requirement that the claimed product have at least 500 consecutive amino acids of SEQ. ID NO:2.

Applicant respectfully disagrees. Claim 1 as originally presented required that the polypeptide be encoded by a DNA that hybridizes under stringent conditions to SEQ. ID NO:1. As the skilled reader will appreciate, this does not mean that the polypeptide has the exact same length as full-length hTRT — indeed, it may very well be shorter, since some of the residues have been deleted so as to eliminate telomerase catalytic activity.

So as to advance prosecution of the application, reference to 500 or more consecutive amino acids has now been removed from claims 1, 4, 5, 16, and 17. The product of claims 4 and 5 comprise full-length telomerase, except for the recited deletion(s). The product of claim 1, 16, and 17 not only lacks telomerase activity, it also is a telomerase inhibitor, thus having other activities of telomerase reverse transcriptase distributed along the length of the hTRT sequence.

Reference to 500 or more consecutive amino acids has been retained in claims 2 and 3, since the function of the claimed polypeptide is tied not to telomerase inhibition activity, but to an ability to elicit hTRT antibody. As explained previously, hTRT peptides containing at least 500 amino acids of hTRT are described in the application as originally presented, and do not introduce new matter. The substitute specification explicitly states that [I]t is sometimes desirable to describe sequence identity between two sequences in reference to a particular length or region . . . over a length of . . . 500 basepairs, amino acids, or other residues (lines 35-39, page 13). Thus, comparing the claimed sequence to the prototype hTRT sequence (SEQ. ID NO:2) along a 500 amino acid region is entirely appropriate.

Claims 1, 3, 10, 2, 4-7, and 12; and subsequently claims 1-7 also stand rejected under the written description requirement of 1.112 ¶ 1 as lacking sufficient description for the scope that is claimed. The Office Action agrees that deletion(s) of 10 or more amino acids is described in the application as filed, but raises questions relating to the wording of the transitional language.

The claims have now been amended in a manner which is believed to address all the concerns raised. Applicant respectfully submits that the scope of the amended claims as explained earlier is fully described in the application as filed

Applicant acknowledges with gratitude that the rejection of these claims under 1.112 ¶ 1 as not enabled by the specification has been withdrawn.

Rejection of claim 13 and its dependents:

These claims are interpreted in the Office Action under 35 USC 1.112 ¶ 6 as meaning any inhibitor that is a protein, peptide, or peptide mimetic and inhibits any activity of telomerase from any organism or man-made. The claims are then rejected under the enablement and written description requirements of 1.112 ¶ 1 as being too broad to be described or enabled by the specification.

Of course, 1.112 ¶ 6 explicitly invokes the species described in the specification, and so the claims cannot lack for literal support if correctly worded. The undersigned understands from the interview that the rejection can be taken as a request that applicant point to the species in the specification that are referred to, consistent with MPEP § 2181(IV).

Telomerase inhibition means listed in the specification are mutants of the hTRT sequence (SEQ. ID NO:2) that contain at least one deletion of 10 amino acids or more listed in Table 1 as having "-" telomerase activity (page 8 of the substitute specification), or the pGRN constructs corresponding thereto (Table 1). Also listed are peptides or peptide mimetics having an amino acid sequence consisting essentially of SEQ. ID NOs:3, 4, and 5 (page 9).

These claims have now been amended to indicate that the product has a means for inhibiting *human* telomerase. The skilled reader will interpret this as indicating that the inhibition means inhibits the activity of human telomerase (specifically, *human telomerase reverse transcriptase* associated with *human telomerase RNA component*) to exhibit telomerase catalytic activity — i.e., the ability of the combined human enzyme to catalyze the elongation of telomere sequences in the presence of a suitable template and substrate nucleotides. Telomerase catalytic activity is an enzyme function, not a structure, not constrained by the species of origin. Appropriate assays for determining telomerase catalytic activity are listed in the specification on page 4, lines 7-13.

Thus, the amended claims are both described and enabled by the specification. To practice the invention, the skilled reader produces or obtains a protein, peptide, or peptide mimetic, as indicated above. They can then determine whether the product has a means for inhibiting the activity of human telomerase using a suitable assay, such as the ones listed on page 4 of the specification.

Withdrawal of all rejections under 35 USC 1.112 is respectfully requested.

Restriction Requirement and Request for Rejoinder:

Applicant gratefully acknowledges the undertaking of the Examiner to rejoin claims 18-20 into the elected group upon allowance of a linking claim.

Claim 21 and new claim 22 depend from and incorporate limitations of product claims in the elected group, and so may be examined in the same group without undue burden. Alternatively, they may be rejoined into the elected group upon determination that the product claims from which they depend are patentable, which is respectfully requested.

Request for Interview

Applicant respectfully requests that all outstanding rejections be reconsidered and withdrawn. The application is believed to be in condition for allowance, and a prompt Notice of Allowance is requested.

In the event that the Examiner determines that there are other matters to be addressed, applicant hereby requests an interview by telephone.

PATENT
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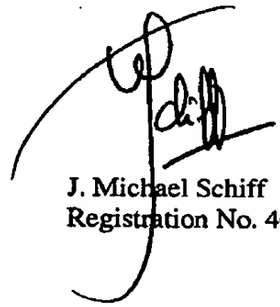
Docket 018/258c

Fees Due

Accompanying this Amendment is a fee transmittal, authorizing the Commissioner to charge applicant's deposit account for the new claims. Also enclosed with this Amendment is authorization to charge the Deposit Account for the extension of time.

Should the Patent Office determine that a further extension of time or any other relief is required for further consideration of this application, applicant hereby petitions for such relief, and authorizes the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,



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